

Remarks

Claims 1-10, 19, 21-26 have been cancelled without prejudice. Claims 11 and 20 have been amended. New claims 27 and 28 have been added. Upon entry of this paper, claims 11, 12-18, 20, 27 and 28 will be pending and under consideration.

Support for the amendments to claim 11 can be found, for example, on page 7, lines 16-20, and in the paragraph bridging pages 11 and 12 of the application as originally filed. Claim 20 has been amended to depend from claim 11. Support for new claim 27 can be found, for example, on page 7, line 20 of the application as filed. Support for new claim 28 can be found, for example, in the first full paragraph of page 15 of the application as originally filed. Applicant believes that the aforementioned amendments and new claims introduce no new matter. The outstanding rejections are addressed in the order in which they appear in the Office Action.

Rejections under 35 U.S.C. § 112, Second Paragraph

According to page 2 of the outstanding Office Action, claims 1-19 presently stand rejected under 35 U.S.C. § 112, second paragraph. Claim 1 and the claims depending therefrom, and claim 19 have been cancelled thereby obviating this rejection as it pertains to these claims. Of the original claim set rejected under 35 U.S.C. § 112, second paragraph, claims 11 and 12-18 remain pending. Applicant respectfully submits that the term “an effective amount” is defined in the paragraph bridging pages 12 and 13 of the application as filed, and, as defined, would not be vague and indefinite to those skilled in the art. Accordingly, Applicant respectfully requests that this rejection be reconsidered and withdrawn.

Rejections Under 35 U.S.C. § 102

According to page 2 of the Office Action, claim 20 presently stands rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,166,202 to Schweizer (the ‘202 Patent) or by Fisgin *et al.* (2000) J. Child Neurol. 15:833-835 (Fisgin). Applicant respectfully traverses this rejection in view of the present amendments and following remarks.

Applicant submits that in order for an anticipation, each and every element of the claimed invention in the claimed combination must be described, expressly or inherently, in a single prior art reference. Applicant submits that neither reference meet this test. In particular, claim 20 has been amended to depend from, and therefore incorporates each and every limitation of claim 11. Applicant submits that not all of the claimed elements of amended claim 20 (for example, the formulation containing from about 15% to about 25% by volume of polyethylene glycol) appear either expressly or inherently within the teachings of the '202 Patent or Fisgin. Accordingly, Applicant respectfully requests that this rejection be reconsidered and withdrawn.

Rejections Under 35 U.S.C. § 103

According to pages 3-4 of the outstanding Office Action, claims 1-4, 6-10, and 21-26 presently stand rejected under 35 U.S.C. § 103 as being obvious over the '202 Patent in view of U.S. Patent No. 6,565,832 to Hanslwanter *et al.* (the '832 Patent). Claims 1-4, 6-10 and 21-26 have been cancelled thereby rendering this rejection moot. Accordingly, Applicant respectfully requests that this rejection be reconsidered and withdraw.

According to pages 4-5 of the outstanding Office Action, claims 5, 11, and 13-19 presently stand rejected under 35 U.S.C. § 103 as being obvious over the '202 Patent and the '832 Patent, as applied to claims 1-4, 6-10 and 20-26, and further in view of U.S. Patent No. 5,554,639 to Craig *et al.* (the '639 Patent). Claims 5 and 19 have been cancelled thereby rendering the rejection of these claims moot. Applicant respectfully traverses this rejection to the extent it is maintained over claims 11 and 13-18, as amended, in view of the following remarks.

The standard for obviousness under 35 U.S.C. § 103 turns on whether the differences between the subject matter sought to be patented and the prior art are such that the subject matter ***as a whole*** would have been obvious at the time the invention was made to a person having ordinary skill in the art to which the subject matter pertains. 35 U.S.C. § 103(a). Applicant submits that the skilled artisan would not have been motivated to combine the teachings of the '202 Patent with those of the '832 Patent and the '639 Patent, as the '832 Patent and the '639 Patent discuss the delivery of active ingredients different from midazolam. The '832 Patent describes the use of a mixture of microcrystalline cellulose and an alkali metal

carboxylalkylcellulose for the delivery of, for example, sympathomimetic amine nasal decongestants (see first and fourth paragraphs of the detailed description). Applicant submits that, to the extent the '832 Patent describes incorporating rheology-modifying agents, for example, polyethylene glycol, into the formulations, the inventors of the '832 Patent describe using "*up to* about 10 percent by weight, more typically about 0.5 to about 5 weight percent" of the rheology-modifying agent (see, Col. 4, lines 20-25). Furthermore, the '639 Patent describes the nasal delivery of 3-[2-(dimethylamino)ethyl]-N-methyl-1H-indole-5-methanesulphonamide sulphate salt (see first page of description), which is different from midazolam. Applicant submits that the formulations of the active ingredients in the '832 Patent and the '639 Patent may not necessarily be extrapolated to intranasal formulations containing midazolam as the active ingredient. In other words, it is not apparent that a formulation optimized for the delivery of one active ingredient can be used to optimize the delivery of a different active ingredient.

Assuming for the sake of argument only that the skilled artisan would have been motivated to combine the teachings of the '202 Patent, '832 Patent, and the '639 Patent, Applicant submits that their combined teachings fail to describe each and every element of the claimed invention, *taken as a whole*. For example, Applicant submits that none of the applied references describe a formulation containing from about 15 % to about 25 % by volume polyethylene glycol and propylene glycol. Accordingly, Applicant submits that the claimed invention, *taken as a whole*, would not have been obvious to the skilled artisan having read the teachings of the '202 Patent, the '821 Patent and the '639 Patent.

In view of the foregoing, Applicant respectfully requests that this rejection be reconsidered and withdrawn.

Double Patenting

According to pages 5-8 of the outstanding Office Action, claims 1-26 presently stand rejected for obviousness-type double patenting over certain claims of U.S. Patent No. 6,610,271. Applicant respectfully requests that this rejection be held in abeyance until the instant claims are considered in condition for allowance but for this double patenting rejection. At that time, Applicant plans to file a terminal disclaimer, if the double patenting rejection is still considered to be appropriate.

Conclusion

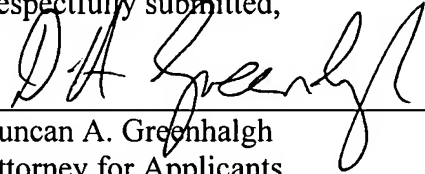
Applicant believes that, in the view of the above amendments and comments, the pending claims are in condition for allowance. Early favorable action is respectfully solicited. The Office is invited to contact the undersigned with any questions about this submission.

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Respectfully submitted,



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